

**TDMS No.** 20537 - 02  
**Test Type:** 90-DAY  
**Route:** INTRADUCTAL CANNULATION  
**Species/Strain:** RATS/F 344/N

**P10: STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS**  
Adenoviral Vector (AdhAQP1)  
**CAS Number:** ADNIRVECAQP

**Date Report Requested:** 09/10/2009  
**Time Report Requested:** 11:35:30  
**First Dose M/F:** NA / 07/25/05  
**Lab:** MBA

F1\_R2\_5Wk\_SSAC

**C Number:** C20537  
**Lock Date:** 11/19/2007  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** 25017 SSAC  
**Removal Date Range:** ALL  
**Treatment Groups:** Include 003 VEHCONTRCOHRTC   Include 008 2-8ADHAQP1COHTC   Include 013 8-9ADHAQP1COHTC  
Include 018 2-11ADHAQP1COHTC  
**Study Gender:** Female  
**TDMSE Version:** 2.1.0

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**SUMMARY OF STATISTICALLY SIGNIFICANT ( $P \leq .05$ ) RESULTS IN THE ANALYSIS OF ADENOVIRAL VECTOR (ADHAQP1)**

**FEMALE RATS**

**Organ**

Salivary Glands: Submandibular Gland, Right

**Morphology**

Inflammation

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## STATISTICAL ANALYSIS OF NON-NEOPLASTIC LESIONS IN RATS(F 344/N) LAST REMOVAL AT 5 WEEKS

Females			
DOSE	VEHCONTRCOHRTC	2-11ADHAQP1COHTC	8-9ADHAQP1COHTC
Salivary Glands: Submandibular Gland, Right Inflammation			
LESION RATES			
OVERALL (a)	0/4 (0%)	2/9 (22%)	3/5 (60%)
POLY-3 RATE (b)	0/4.00	2/9.00	3/5.00
POLY-3 PERCENT (g)	0%	22.2%	60%
INT SACRIFICE 1	0/4 (0%	2/9 (22%	3/5 (60%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	---	29 (I)	29 (I)
STATISTICAL TESTS			
POLY 3	P=0.055	P=0.427	P=0.088
POLY 1.5	P=0.055	P=0.427	P=0.088
POLY 6	P=0.055	P=0.427	P=0.088
COCH-ARM / FISHERS	P=0.063	P=0.462	P=0.119
MAX-ISO-POLY-3	P=0.034*	P=0.202	P=0.020*

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Females			
DOSE	VEHCONTRCOHRTC	2-11ADHAQP1COHTC	8-9ADHAQP1COHTC
Salivary Glands: Submandibular Gland, Right Regeneration			
LESION RATES			
OVERALL (a)	4/4 (100%)	9/9 (100%)	5/5 (100%)
POLY-3 RATE (b)	4/4.00	9/9.00	5/5.00
POLY-3 PERCENT (g)	100%	100%	100%
INT SACRIFICE 1	4/4 (100%	9/9 (100%	5/5 (100%
TERMINAL (d)	0/0 (0%)	0/0 (0%)	0/0 (0%)
FIRST INCIDENCE	29 (I)	29 (I)	29 (I)
STATISTICAL TESTS			
POLY 3	(e)	(e)	(e)
POLY 1.5	(e)	(e)	(e)
POLY 6	(e)	(e)	(e)
COCH-ARM / FISHERS	(e)	(e)	(e)
MAX-ISO-POLY-3	(e)	(e)	(e)

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**LEGEND**

- (a) Number of tumor-bearing animals/number of animals examined at site.
  - (b) Number of tumor-bearing animals/Poly-3 number
  - (d) Observed incidence at terminal kill.
  - (e) Value of Statistic cannot be computed.
  - (f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group.
  - (g) Poly-3 adjusted lifetime tumor incidence.
  - (I) Interim sacrifice
  - (T) Terminal sacrifice
  - # Tumor rates based on numbers of animals necropsied.
  - \* To the right of any statistical result, indicates significance at ( $P \leq 0.05$ ).
  - \*\* To the right of any statistical result, indicates significance at ( $P \leq 0.01$ ).
  - N Indicates a negative trend for all tests
- The Cochran-Armitage and Fishers exact tests compare directly the overall incidence rates.

\*\*\* END OF REPORT \*\*\*